

AMENDED IN SENATE AUGUST 21, 2014
AMENDED IN SENATE AUGUST 19, 2014
AMENDED IN ASSEMBLY MAY 23, 2014
AMENDED IN ASSEMBLY MARCH 19, 2014

CALIFORNIA LEGISLATURE—2013–14 REGULAR SESSION

ASSEMBLY BILL

No. 1559

Introduced by Assembly Member Pan
(Principal coauthors: Assembly Members Fox and Gatto)
(Coauthors: Assembly Members Bloom, Brown, Chesbro,
Maienschein, Nazarian, and Wieckowski)
(Coauthors: Senators Fuller, Hill, *Nielsen*, Vidak, and Wyland)

January 28, 2014

An act to ~~amend, repeal, and add~~ *amend* Sections 124977 and 125001 of the Health and Safety Code, relating to public health, and making an appropriation therefor.

LEGISLATIVE COUNSEL'S DIGEST

AB 1559, as amended, Pan. Newborn screening program.

Existing law requires the State Department of Public Health to establish a program for the development, provision, and evaluation of genetic disease testing.

Existing law establishes the continuously appropriated Genetic Disease Testing Fund (GDTF), consisting of fees paid for newborn screening tests and states the intent of the Legislature that all costs of the genetic disease testing program be fully supported by fees paid for newborn screening tests, which are deposited in the GDTF. Existing law also authorizes moneys in the GDTF to be used for the expansion of the

Genetic Disease Branch Screening Information System to include cystic fibrosis, biotinidase, and severe combined immunodeficiency (SCID) and exempts the expansion of contracts for this purpose from certain provisions of the Public Contract Code, the Government Code, and the State Administrative Manual, as specified.

This bill ~~would, until January 1, 2018,~~ *would* require the department to expand statewide screening of newborns to include screening for adrenoleukodystrophy (ALD) *as soon as ALD is adopted by the federal Recommended Uniform Screening Panel (RUSP)*. By expanding the purposes for which moneys from the fund may be expended, this bill would make an appropriation.

Vote: majority. Appropriation: yes. Fiscal committee: yes.
State-mandated local program: no.

The people of the State of California do enact as follows:

1 SECTION 1. Section 124977 of the Health and Safety Code
2 is amended to read:
3 124977. (a) It is the intent of the Legislature that, unless
4 otherwise specified, the genetic disease testing program carried
5 out pursuant to this chapter be fully supported from fees collected
6 for services provided by the program.
7 (b) (1) The department shall charge a fee to all payers for any
8 tests or activities performed pursuant to this chapter. The amount
9 of the fee shall be established by regulation and periodically
10 adjusted by the director in order to meet the costs of this chapter.
11 Notwithstanding any other law, any fees charged for prenatal
12 screening and followup services provided to persons enrolled in
13 the Medi-Cal program, health care service plan enrollees, or
14 persons covered by health insurance policies, shall be paid in full
15 and deposited in the Genetic Disease Testing Fund or the Birth
16 Defects Monitoring Fund consistent with this section, subject to
17 all terms and conditions of each enrollee's or insured's health care
18 service plan or insurance coverage, whichever is applicable,
19 including, but not limited to, copayments and deductibles
20 applicable to these services, and only if these copayments,
21 deductibles, or limitations are disclosed to the subscriber or enrollee
22 pursuant to the disclosure provisions of Section 1363.
23 (2) The department shall expeditiously undertake all steps
24 necessary to implement the fee collection process, including

1 personnel, contracts, and data processing, so as to initiate the fee
2 collection process at the earliest opportunity.

3 (3) Effective for services provided on and after July 1, 2002,
4 the department shall charge a fee to the hospital of birth, or, for
5 births not occurring in a hospital, to families of the newborn, for
6 newborn screening and followup services. The hospital of birth
7 and families of newborns born outside the hospital shall make
8 payment in full to the Genetic Disease Testing Fund. The
9 department shall not charge or bill Medi-Cal beneficiaries for
10 services provided under this chapter.

11 (4) (A) The department shall charge a fee for prenatal screening
12 to support the pregnancy blood sample storage, testing, and
13 research activities of the Birth Defects Monitoring Program.

14 (B) The prenatal screening fee for activities of the Birth Defects
15 Monitoring Program shall be ten dollars (\$10).

16 (5) The department shall set guidelines for invoicing, charging,
17 and collecting from approved researchers the amount necessary
18 to cover all expenses associated with research application requests
19 made under this section, data linkage, retrieval, data processing,
20 data entry, reinventory, and shipping of blood samples or their
21 components, and related data management.

22 (6) The only funds from the Genetic Disease Testing Fund that
23 may be used for the purpose of supporting the pregnancy blood
24 sample storage, testing, and research activities of the Birth Defects
25 Monitoring Program are those prenatal screening fees assessed
26 and collected prior to the creation of the Birth Defects Monitoring
27 Program Fund specifically to support those Birth Defects
28 Monitoring Program activities.

29 (7) The Birth Defects Monitoring Program Fund is hereby
30 created as a special fund in the State Treasury. Fee revenues that
31 are collected pursuant to paragraph (4) shall be deposited into the
32 fund and shall be available upon appropriation by the Legislature
33 to support the pregnancy blood sample storage, testing, and
34 research activities of the Birth Defects Monitoring Program.
35 Notwithstanding Section 16305.7 of the Government Code, interest
36 earned on funds in the Birth Defects Monitoring Program Fund
37 shall be deposited as revenue into the fund to support the Birth
38 Defects Monitoring Program.

39 (c) (1) The Legislature finds that timely implementation of
40 changes in genetic screening programs and continuous maintenance

1 of quality statewide services requires expeditious regulatory and
2 administrative procedures to obtain the most cost-effective
3 electronic data processing, hardware, software services, testing
4 equipment, and testing and followup services.

5 (2) The expenditure of funds from the Genetic Disease Testing
6 Fund for these purposes shall not be subject to Section 12102 of,
7 and Chapter 2 (commencing with Section 10290) of Part 2 of
8 Division 2 of, the Public Contract Code, or to Division 25.2
9 (commencing with Section 38070). The department shall provide
10 the Department of Finance with documentation that equipment
11 and services have been obtained at the lowest cost consistent with
12 technical requirements for a comprehensive high-quality program.

13 (3) The expenditure of funds from the Genetic Disease Testing
14 Fund for implementation of the Tandem Mass Spectrometry
15 screening for fatty acid oxidation, amino acid, and organic acid
16 disorders, and screening for congenital adrenal hyperplasia may
17 be implemented through the amendment of the Genetic Disease
18 Branch Screening Information System contracts and shall not be
19 subject to Chapter 3 (commencing with Section 12100) of Part 2
20 of Division 2 of the Public Contract Code, Article 4 (commencing
21 with Section 19130) of Chapter 5 of Part 2 of Division 5 of Title
22 2 of the Government Code, and any policies, procedures,
23 regulations, or manuals authorized by those laws.

24 (4) The expenditure of funds from the Genetic Disease Testing
25 Fund for the expansion of the Genetic Disease Branch Screening
26 Information System to include cystic fibrosis, biotinidase, severe
27 combined immunodeficiency (SCID), and adrenoleukodystrophy
28 (ALD) may be implemented through the amendment of the Genetic
29 Disease Branch Screening Information System contracts, and shall
30 not be subject to Chapter 2 (commencing with Section 10290) or
31 Chapter 3 (commencing with Section 12100) of Part 2 of Division
32 2 of the Public Contract Code, Article 4 (commencing with Section
33 19130) of Chapter 5 of Part 2 of Division 5 of Title 2 of the
34 Government Code, or Sections 4800 to 5180, inclusive, of the
35 State Administrative Manual as they relate to approval of
36 information technology projects or approval of increases in the
37 duration or costs of information technology projects. This
38 paragraph shall apply to the design, development, and
39 implementation of the expansion, and to the maintenance and
40 operation of the Genetic Disease Branch Screening Information

1 System, including change requests, once the expansion is
2 implemented.

3 (d) (1) The department may adopt emergency regulations to
4 implement and make specific this chapter in accordance with
5 Chapter 3.5 (commencing with Section 11340) of Part 1 of Division
6 3 of Title 2 of the Government Code. For the purposes of the
7 Administrative Procedure Act, the adoption of regulations shall
8 be deemed an emergency and necessary for the immediate
9 preservation of the public peace, health and safety, or general
10 welfare. Notwithstanding Chapter 3.5 (commencing with Section
11 11340) of Part 1 of Division 3 of Title 2 of the Government Code,
12 these emergency regulations shall not be subject to the review and
13 approval of the Office of Administrative Law. Notwithstanding
14 Sections 11346.1 and 11349.6 of the Government Code, the
15 department shall submit these regulations directly to the Secretary
16 of State for filing. The regulations shall become effective
17 immediately upon filing by the Secretary of State. Regulations
18 shall be subject to public hearing within 120 days of filing with
19 the Secretary of State and shall comply with Sections 11346.8 and
20 11346.9 of the Government Code or shall be repealed.

21 (2) The Office of Administrative Law shall provide for the
22 printing and publication of these regulations in the California Code
23 of Regulations. Notwithstanding Chapter 3.5 (commencing with
24 Section 11340) of Part 1 of Division 3 of Title 2 of the Government
25 Code, the regulations adopted pursuant to this chapter shall not be
26 repealed by the Office of Administrative Law and shall remain in
27 effect until revised or repealed by the department.

28 (3) The Legislature finds and declares that the health and safety
29 of California newborns is in part dependent on an effective and
30 adequately staffed genetic disease program, the cost of which shall
31 be supported by the fees generated by the program.

32 ~~(e) This section shall remain in effect only until January 1, 2018,~~
33 ~~and as of that date is repealed, unless a later enacted statute, that~~
34 ~~is enacted before January 1, 2018, deletes or extends that date.~~

35 SEC. 2. ~~Section 124977 is added to the Health and Safety Code,~~
36 ~~to read:~~

37 ~~124977. (a) It is the intent of the Legislature that, unless~~
38 ~~otherwise specified, the genetic disease testing program carried~~
39 ~~out pursuant to this chapter be fully supported from fees collected~~
40 ~~for services provided by the program.~~

~~(b) (1) The department shall charge a fee to all payers for any tests or activities performed pursuant to this chapter. The amount of the fee shall be established by regulation and periodically adjusted by the director in order to meet the costs of this chapter. Notwithstanding any other provision of law, any fees charged for prenatal screening and followup services provided to persons enrolled in the Medi-Cal program, health care service plan enrollees, or persons covered by health insurance policies, shall be paid in full and deposited in the Genetic Disease Testing Fund or the Birth Defects Monitoring Fund consistent with this section, subject to all terms and conditions of each enrollee's or insured's health care service plan or insurance coverage, whichever is applicable, including, but not limited to, copayments and deductibles applicable to these services, and only if these copayments, deductibles, or limitations are disclosed to the subscriber or enrollee pursuant to the disclosure provisions of Section 1363.~~

~~(2) The department shall expeditiously undertake all steps necessary to implement the fee collection process, including personnel, contracts, and data processing, so as to initiate the fee collection process at the earliest opportunity.~~

~~(3) Effective for services provided on and after July 1, 2002, the department shall charge a fee to the hospital of birth, or, for births not occurring in a hospital, to families of the newborn, for newborn screening and followup services. The hospital of birth and families of newborns born outside the hospital shall make payment in full to the Genetic Disease Testing Fund. The department shall not charge or bill Medi-Cal beneficiaries for services provided under this chapter.~~

~~(4) (A) The department shall charge a fee for prenatal screening to support the pregnancy blood sample storage, testing, and research activities of the Birth Defects Monitoring Program.~~

~~(B) The prenatal screening fee for activities of the Birth Defects Monitoring Program shall be ten dollars (\$10).~~

~~(5) The department shall set guidelines for invoicing, charging, and collecting from approved researchers the amount necessary to cover all expenses associated with research application requests made under this section, data linkage, retrieval, data processing, data entry, reinventory, and shipping of blood samples or their components and related data management.~~

1 ~~(6) The only funds from the Genetic Disease Testing Fund that~~
2 ~~may be used for the purpose of supporting the pregnancy blood~~
3 ~~sample storage, testing, and research activities of the Birth Defects~~
4 ~~Monitoring Program are those prenatal screening fees assessed~~
5 ~~and collected prior to the creation of the Birth Defects Monitoring~~
6 ~~Program Fund specifically to support those Birth Defects~~
7 ~~Monitoring Program activities.~~

8 ~~(7) The Birth Defects Monitoring Program Fund is hereby~~
9 ~~created as a special fund in the State Treasury. Fee revenues that~~
10 ~~are collected pursuant to paragraph (4) shall be deposited into the~~
11 ~~fund and shall be available upon appropriation by the Legislature~~
12 ~~to support the pregnancy blood sample storage, testing, and~~
13 ~~research activities of the Birth Defects Monitoring Program.~~
14 ~~Notwithstanding Section 16305.7 of the Government Code, interest~~
15 ~~earned on funds in the Birth Defects Monitoring Program Fund~~
16 ~~shall be deposited as revenue into the fund to support the Birth~~
17 ~~Defects Monitoring Program.~~

18 ~~(e) (1) The Legislature finds that timely implementation of~~
19 ~~changes in genetic screening programs and continuous maintenance~~
20 ~~of quality statewide services requires expeditious regulatory and~~
21 ~~administrative procedures to obtain the most cost-effective~~
22 ~~electronic data processing, hardware, software services, testing~~
23 ~~equipment, and testing and followup services.~~

24 ~~(2) The expenditure of funds from the Genetic Disease Testing~~
25 ~~Fund for these purposes shall not be subject to Section 12102 of,~~
26 ~~and Chapter 2 (commencing with Section 10290) of Part 2 of~~
27 ~~Division 2 of, the Public Contract Code, or to Division 25.2~~
28 ~~(commencing with Section 38070). The department shall provide~~
29 ~~the Department of Finance with documentation that equipment~~
30 ~~and services have been obtained at the lowest cost consistent with~~
31 ~~technical requirements for a comprehensive high-quality program.~~

32 ~~(3) The expenditure of funds from the Genetic Disease Testing~~
33 ~~Fund for implementation of the Tandem Mass Spectrometry~~
34 ~~screening for fatty acid oxidation, amino acid, and organic acid~~
35 ~~disorders, and screening for congenital adrenal hyperplasia may~~
36 ~~be implemented through the amendment of the Genetic Disease~~
37 ~~Branch Screening Information System contracts and shall not be~~
38 ~~subject to Chapter 3 (commencing with Section 12100) of Part 2~~
39 ~~of Division 2 of the Public Contract Code, Article 4 (commencing~~
40 ~~with Section 19130) of Chapter 5 of Part 2 of Division 5 of Title~~

~~2 of the Government Code, and any policies, procedures, regulations or manuals authorized by those laws.~~

~~(4) The expenditure of funds from the Genetic Disease Testing Fund for the expansion of the Genetic Disease Branch Screening Information System to include cystic fibrosis, biotinidase, and severe combined immunodeficiency (SCID) may be implemented through the amendment of the Genetic Disease Branch Screening Information System contracts, and shall not be subject to Chapter 2 (commencing with Section 10290) or Chapter 3 (commencing with Section 12100) of Part 2 of Division 2 of the Public Contract Code, Article 4 (commencing with Section 19130) of Chapter 5 of Part 2 of Division 5 of Title 2 of the Government Code, or Sections 4800 to 5180, inclusive, of the State Administrative Manual as they relate to approval of information technology projects or approval of increases in the duration or costs of information technology projects. This paragraph shall apply to the design, development, and implementation of the expansion, and to the maintenance and operation of the Genetic Disease Branch Screening Information System, including change requests, once the expansion is implemented.~~

~~(d) (1) The department may adopt emergency regulations to implement and make specific this chapter in accordance with Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code. For the purposes of the Administrative Procedure Act, the adoption of regulations shall be deemed an emergency and necessary for the immediate preservation of the public peace, health and safety, or general welfare. Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, these emergency regulations shall not be subject to the review and approval of the Office of Administrative Law. Notwithstanding Sections 11346.1 and 11349.6 of the Government Code, the department shall submit these regulations directly to the Secretary of State for filing. The regulations shall become effective immediately upon filing by the Secretary of State. Regulations shall be subject to public hearing within 120 days of filing with the Secretary of State and shall comply with Sections 11346.8 and 11346.9 of the Government Code or shall be repealed.~~

~~(2) The Office of Administrative Law shall provide for the printing and publication of these regulations in the California Code~~

1 of Regulations. Notwithstanding Chapter 3.5 (commencing with
2 Section 11340) of Part 1 of Division 3 of Title 2 of the Government
3 Code, the regulations adopted pursuant to this chapter shall not be
4 repealed by the Office of Administrative Law and shall remain in
5 effect until revised or repealed by the department.

6 (3) ~~The Legislature finds and declares that the health and safety~~
7 ~~of California newborns is in part dependent on an effective and~~
8 ~~adequately staffed genetic disease program, the cost of which shall~~
9 ~~be supported by the fees generated by the program.~~

10 (e) ~~This section shall become operative on January 1, 2018.~~

11 SEC. 3.

12 SEC. 2. Section 125001 of the Health and Safety Code is
13 amended to read:

14 125001. (a) The department shall establish a program for the
15 development, provision, and evaluation of genetic disease testing,
16 and may provide laboratory testing facilities or make grants to,
17 contract with, or make payments to, any laboratory that it deems
18 qualified and cost effective to conduct testing or with any metabolic
19 specialty clinic to provide necessary treatment with qualified
20 specialists. The program shall provide genetic screening and
21 followup services for persons who have the screening.

22 (b) The department shall expand statewide screening of
23 newborns to include tandem mass spectrometry screening for fatty
24 acid oxidation, amino acid, organic acid disorders, and congenital
25 adrenal hyperplasia as soon as possible. The department shall
26 provide information with respect to these disorders and available
27 testing resources to all women receiving prenatal care and to all
28 women admitted to a hospital for delivery. If the department is
29 unable to provide this statewide screening by August 1, 2005, the
30 department shall temporarily obtain these testing services through
31 a competitive bid process from one or more public or private
32 laboratories that meet the department's requirements for testing,
33 quality assurance, and reporting. If the department determines that
34 contracting for these services is more cost effective, and meets the
35 other requirements of this chapter, than purchasing the tandem
36 mass spectrometry equipment themselves, the department shall
37 contract with one or more public or private laboratories.

38 (c) The department shall expand statewide screening of
39 newborns to include screening for severe combined
40 immunodeficiency (SCID) as soon as possible. In implementing

1 the SCID screening test, the department shall also screen for other
2 T-cell lymphopenias that are detectable as a result of screening
3 for SCID, insofar as it does not require additional costs or
4 equipment beyond that needed to test for SCID.

5 (d) The department shall expand statewide screening of
6 newborns to include screening for adrenoleukodystrophy (ALD)
7 as soon as possible. *ALD is adopted by the federal Recommended*
8 *Uniform Screening Panel (RUSP).*

9 ~~(e) This section shall remain in effect only until January 1, 2018,~~
10 ~~and as of that date is repealed, unless a later enacted statute, that~~
11 ~~is enacted before January 1, 2018, deletes or extends that date.~~

12 SEC. 4. ~~Section 125001 is added to the Health and Safety Code,~~
13 ~~to read:~~

14 ~~125001. (a) The department shall establish a program for the~~
15 ~~development, provision, and evaluation of genetic disease testing,~~
16 ~~and may provide laboratory testing facilities or make grants to,~~
17 ~~contract with, or make payments to, any laboratory that it deems~~
18 ~~qualified and cost-effective to conduct testing or with any~~
19 ~~metabolic specialty clinic to provide necessary treatment with~~
20 ~~qualified specialists. The program shall provide genetic screening~~
21 ~~and followup services for persons who have the screening.~~

22 ~~(b) The department shall expand statewide screening of~~
23 ~~newborns to include tandem mass spectrometry screening for fatty~~
24 ~~acid oxidation, amino acid, and organic acid disorders and~~
25 ~~congenital adrenal hyperplasia as soon as possible. The department~~
26 ~~shall provide information with respect to these disorders and~~
27 ~~available testing resources to all women receiving prenatal care~~
28 ~~and to all women admitted to a hospital for delivery. If the~~
29 ~~department is unable to provide this statewide screening by August~~
30 ~~1, 2005, the department shall temporarily obtain these testing~~
31 ~~services through a competitive bid process from one or more public~~
32 ~~or private laboratories that meet the department's requirements~~
33 ~~for testing, quality assurance, and reporting. If the department~~
34 ~~determines that contracting for these services is more cost-effective,~~
35 ~~and meets the other requirements of this chapter, than purchasing~~
36 ~~the tandem mass spectrometry equipment themselves, the~~
37 ~~department shall contract with one or more public or private~~
38 ~~laboratories.~~

39 ~~(c) The department shall expand statewide screening of~~
40 ~~newborns to include screening for severe combined~~

- 1 immunodeficiency (SCID) as soon as possible. In implementing
- 2 the SCID screening test, the department shall also screen for other
- 3 T-cell lymphopenias that are detectable as a result of screening
- 4 for SCID, insofar as it does not require additional costs or
- 5 equipment beyond that needed to test for SCID.
- 6 (d) This section shall become operative on January 1, 2018.